

EXHIBIT

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION

MDL NO. 2187

IN RE: AMERICAN MEDICAL SYSTEMS, INC., PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION

MDL NO. 2325

IN RE: BOSTON SCIENTIFIC, PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION

MDL NO. 2326

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION

MDL NO. 2327

IN RE: COLOPLAST PELVIC
REPAIR SYSTEM PRODUCTS LIABILITY
LITIGATION

MDL NO. 2387

THIS DOCUMENT RELATES TO ALL CASES

**AFFIDAVIT OF KLINE & SPECTER, P.C. IN CONNECTION WITH THE REQUEST FOR
ALLOCATION OF AGGREGATE COMMON BENEFIT AND COSTS AWARD**

I, Lee B. Balefsky, aver:

I. INTRODUCTION

1. I am a partner with the law firm of Kline & Specter, P.C. ("Kline & Specter").
2. This Affidavit is based upon personal knowledge and information provided by others in our firm
at my request.

3. The primary address of the law firm identified in paragraph one (1) above is 1525 Locust Street, Philadelphia, PA.
4. I have complied with all applicable Pre-Trial Orders in all material aspects and the law firm identified herein has submitted true and correct time and expense submissions pursuant to the Court's Pre-Trial Orders. This affidavit is submitted on behalf of Kline & Specter.
5. Kline & Specter is a nationally recognized law firm concentrating in personal injury, made up of forty-one (41) attorneys including five doctor-lawyers.
6. Kline & Specter has been an involved party in the Pelvic Mesh litigation since 2012. In the course of the pelvic mesh litigation, Kline and Specter has represented over 3,000 women who suffered injuries as a result of the defendants' allegedly defective pelvic mesh products.
7. Kline & Specter has made substantial financial contributions to this litigation, including MDL fee assessments totaling \$350,000, advancement of common benefit costs of \$1,505,071.58, assessment to the New Jersey TVM committee in the amount of \$115,000, advancing several millions of dollars on behalf of injured clients, as well as many thousands of hours of firm attorneys and staff.
8. I personally serve on the Plaintiffs' Steering Committee ("PSC") in the MDL and attended every MDL Status Conference.
9. In addition to serving on the PSC in these MDL's, I serve on the New Jersey State Court Discovery Committee for mesh and as liaison counsel in the Philadelphia Court of Common Pleas Pelvic Mesh Mass Tort Program.
10. Kline & Specter attorneys have had a critically important role in all aspects of the pelvic mesh litigation, particularly the Ethicon litigation. While acting through the Pelvic Mesh Federal MDL, the New Jersey pelvic mesh program, the Delaware pelvic mesh program, and the Philadelphia Mass Tort Litigation, our firm has provided extensive services for the common

benefit for all pelvic mesh litigants as follows: participation on multiple committees, including the Ethicon MDL and New Jersey Discovery Committees; performance of factual discovery including extensive review of documents and depositions; legal research, briefing, drafting, and argument; preparation of deposition cuts to be played at trial; email, telephone and in person conferences with co-counsel regarding the discovery, legal and trial strategy; expert preparation, reports and presentation for deposition; medical and scientific research; review of cases for several bellwether trials; preparation of trial packages; and lead trial counsel in pelvic mesh trials. The common benefit activities performed by Kline & Specter attorneys are detailed extensively below.

11. Twenty-four (24) Kline & Specter attorneys have participated in this litigation including:

Thomas R. Kline, Founding Partner; Shanin Specter, Founding Partner; Lee B. Balefsky, Partner; Charles Becker, Partner; Christopher Gomez, Partner; James J. Waldenberger, Partner; Michael Trunk, Partner; Lisa Dagostino, M.D., Partner; Barry Magen, M.D., Partner; Kila Baldwin, Partner; Regan Safier, Partner; Robert Leoni, Partner; Kristen Sipala, Associate; Christine Clarke, Associate; Priscilla Jimenez, Associate; Colin Burke, Associate; Patrick Fitzgerald, Associate; Andra Laidacker, Associate; Tracie Palmer, Associate; Elia Robertson, Associate; Roger Cameron, Attorney; Catherine Foley, Attorney; Jonathan Goodall, Attorney; Ebiho Ahonkai, Attorney.

12. Attorneys from Kline & Specter, including founding partners Thomas R. Kline and Shanin Specter have successfully obtained five (5) verdicts totaling over \$110 million:

- a. *Hammons v. Ethicon*, No. 130503913, Pa. Comm. Pls., Philadelphia Co. (2015):
\$12,500,000 verdict. (\$5.5 million in compensatory damages, \$7 million in punitive damages.) Prolift.
- b. *Carlino v. Ethicon*, Case No. 130603470. Pa. Comm. Pls., Philadelphia Co. (2016).
\$13.5 million verdict. (\$3.25 million in compensatory damages for Mrs. Carlino, \$250,000 to Mr. Carlino for loss of consortium, and \$10 million in punitive damages.) TVT.

- c. *Engelmann v. Ethicon*, Case No. No. 140305384. Pa. Comm. Pls., Philadelphia (2017). **\$20 million verdict.** (\$2.5 million in compensatory damages and \$17.5 million in punitive damages.) TVT Secur.
- d. *Beltz v. Ethicon*, Case No. 130603835, Pa. Comm. Pls., Philadelphia Co. (2017). **\$2.16 million verdict.** (\$2.16 million in compensatory damages) Prolift.
- e. *Ebaugh v. Ethicon*, Case No. 130700866. Pa. Comm. Pls., Philadelphia Co. (2017) **\$57.1 million verdict.** (\$7.1 million in compensatory damages and \$50 million in punitive damages.) TVT and TVT Secur.¹

13. Kline & Specter continues to defend these verdicts on appeal.

14. During these trials, our firm has obtained important legal rulings. These rulings, discussed in Section V below, have been vital to this litigation, relied upon by numerous Plaintiffs' attorneys trying cases throughout this litigation, and continue to benefit the entire litigation.

II. DEVELOPMENT OF THE CASE THROUGH DISCOVERY

15. The pelvic mesh litigation against Ethicon was originally coordinated between the MDL and the New Jersey state court litigation.

16. Beginning in 2012, attorneys at Kline & Specter devoted thousands of hours to the review of documents produced by defendants, inspecting millions of pages of documents and providing subjective coding of those documents. All reviewing attorneys were trained on the issues in the litigation for effective and efficient searching and coding. The reviewers were also trained extensively on the Crivella system and the necessary coding.

17. The attorneys of Kline & Specter performed significant and substantial services with regard to this review of documents produced by the various defendants (primarily Ethicon) in this litigation, including but not limited to:

¹ While the *Engleman*, *Beltz*, and *Ebaugh* cases were after 2016, all hours submitted by Kline & Specter are for work performed before the cut-off date for submission of common benefit time.

- a. Analyzed document productions including analyzing productions for deficiencies and/or missing productions.
 - b. Prepared and served interrogatories and requests for the production of documents.
 - c. Helped draft discovery motions and responses.
 - d. Established the identity of document custodians. Negotiated with defendants to produce additional document custodians.
 - e. Identified key fact witnesses for depositions.
18. Because Kline & Specter was involved early in this litigation, many of the key documents found by Kline & Specter attorneys were used in multiple depositions and trials and have proved crucial in developing case strategy from the onset of this litigation.
19. Kline and Specter attorneys were repeatedly singled out by those in leadership as a critical part of the document analysis review team and the discovery of key documents. Kline & Specter attorney Roger Cameron was repeatedly recognized to be one the top document reviewers and one of the individuals most knowledgeable about the factual aspects of this litigation. (*See* May 14, 2013 email from Wagstaff & Cartmell Attorney, Andrew N. Faes to Kline & Specter Attorney, Roger Cameron: “Roger, I know we’ve been abusing you lately, but that’s just because you’re so darn good. I have one more favor to ask: Can you look and see if you can find any more Clinical Expert Reports for the TVT Classic. . . ?”, attached as Exhibit “1”; *see also* May 29, 2013 email from Wagstaff & Cartmell Named Partner, Thomas P. Cartmell, to Roger Cameron: “Hope you don’t mind me bothering you so much, but you and Andy get me the answers I need so fast, so I try not to bog one down with everything! Quick question- . . . can you answer these questions and if you have any other documents that have to do with doctors telling them they need to study TVT-s, shoot me that too!” attached as Exhibit “2.”)

20. The following is just a sample of the coordinated efforts between Kline & Specter attorneys and lead members of the PSC which formulated the key strategy to developing the work for the benefit of all plaintiffs in this litigation:

a. At the request of Thomas Cartmell, Kline & Specter attorneys provided key documents to MDL attorneys regarding the acquisition of Medscand's TVT system in a September 6, 2013 email: "This document is a treasure trove of substantive information about the acquisition of Medscand's TVT System and this shift of its manufacturing from Sweden to Neuchatel. It is also a road map for the further avenues of discovery and prod of the multiple failures of JnJ to respond to our discovery request and to manipulate the process to our prejudice. . . " Thomas Cartmell responds with: "Roger, this and your earlier email are great. I am thinking we will likely need to draft either a letter or RFP for the documents that haven't been produced. **Will you please handle?** Actually, the more I think about it, let's just do an RFP so we can at least get formal answers. . ." (See September 6, 2013 email, attached as Exhibit "3.")

b. Additionally, it was Mr. Cameron who discovered the key "Destroy after reading" email on spoliation from Ethicon employee Dan Smith. (See January 14, 2014 email from Roger Cameron to Bryan Aylstock, et al., attached as Exhibit "4.")

21. Kline & Specter was involved in the development of most difficult and central issues in this litigation. Because of our experience with discovery and trial of complex cases, including pharmaceutical cases, we were assigned a substantial role in the development of the liability and causation core theories. Kline & Specter attorneys were important in identifying key

corporate witnesses for deposition and assisted in the depositions of virtually all of the Ethicon corporate witnesses, including the following individuals:

A. Ethicon Personnel Depositions:

- **Dharini Amin:** Ethicon, Marketing Director. (February 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Giselle Bonet:** Ethicon, World Wide Marketing Director, Women's Health. (March 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Zenobia Walji:** Ethicon, Worldwide Strategic Planning. (March 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Sungyoon Rha:** Ethicon, Worldwide Supplier Quality Manager. (March 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Stacy Hoffman:** Ethicon, Senior Manager, Sales Policy and Procedures. (March 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Catherine Beath:** Ethicon, Worldwide Vice President Quality Assurance, Regulatory Affairs. (March 2012. Attorney Roger Cameron: document review; deposition preparation; provided key documents and analysis, attended deposition.)
- **Richard Hutchinson:** Ethicon, Senior Research Fellow. (March 2012. Attorney Kristen Loerch: document review; deposition preparation; identified key players noted in testimony; continued preparation of comprehensive list with key information for use in future depositions; attended deposition.)
- **Jennifer L. Payne, M.D.:** Ethicon Expert Witness. (March 2012. Attorney Roger Cameron: attended deposition; summarized testimony for future depositions.)
- **Vincenza Zaddam:** Ethicon, Engineer. (April 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Mark Yale:** Ethicon, Group Director, Franchise Quality Engineering, Quality Systems and Post Market Surveillance. (April 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Piet Hinoul:** Ethicon, Vice President of Medical Affairs. (April 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Judi Gauld:** Ethicon, Head of Clinical and Medical Affairs. (April 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)
- **Dan Lamont:** Ethicon, Director of Quality and Regulatory Compliance. (May 2012. Attorney Roger Cameron, document review; deposition preparation; Mr. Cameron attended deposition.)
- **Aaron Kirkemo:** Ethicon, Medical Director. (May 2012. Attorney Kristen Loerch: document review; deposition preparation; attended deposition; prepared summary of testimony for future use.)
- **Dan Smith:** Ethicon, Engineering Fellow. (May 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition.)

- **Kevin Mahar:** Ethicon, Vice President of Sales. (May 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Sean O'Bryan:** Ethicon, Regulatory Affairs. (May 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Martin Weisberg, M.D.:** Ethicon, Medical Director. (May 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Axel Arnaud, M.D.:** Ethicon, Director of Medical Affairs. (June 2012. Attorney Roger Cameron: document review; deposition preparation; analyzed Arnaud document productions; attended deposition; prepared summary of testimony.)
- **Brian Kanerviko:** Ethicon, Worldwide Director of Regulatory Affairs. (June 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Dan Minsker:** Food and Drug Administration Office of Criminal Affairs. (August 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Jeffrey Everett:** Ethicon, Engineer. (October 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **David Robinson:** Ethicon, Worldwide Medical Director. (March 2012. Partner Lee Balefsky, Attorney Roger Cameron: document review; deposition preparation; Mr. Balefsky attended the deposition and examined the witness.)
- **Gary Pruden:** Johnson & Johnson, Chairman, Medical Devices. (August 2012. Partner Lee Balefsky, Attorney Roger Cameron: document review; deposition preparation; analyzed Arnaud document productions; Mr. Balefsky attended the deposition and examined the witness.)
- **Judi Gauld:** Ethicon, Vice President, Clinical Research & Development. (April 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Alex Gorsky:** Johnson & Johnson, Chief Executive Officer. (August 2012. Partner Lee Balefsky, Attorney Roger Cameron: document review; deposition preparation; analyzed Arnaud document productions; Mr. Balefsky attended deposition.)
- **Scott Ciarrocca:** Ethicon, Director, Research & Development. (September 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Meng Chen:** Ethicon, Medical Director. (September 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Daniel Burkley:** Ethicon, Principal Scientist. (October 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Thomas A. Barbolt, Ph.D.:** Ethicon, Distinguished Research Fellow. (July 2013. Attorney Roger Cameron: review, analyze key documents and database for deposition; attended deposition.)

- **Sheri McCoy:** Johnson & Johnson, Vice President of the Executive Committee. (October 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Peter Cecchini:** Ethicon, Regulatory Affairs. (October 2013. Paralegal Jai Dehadrai: document review; deposition preparation; attended deposition via phone; prepared summary of testimony.)
- **Gene Kammerer:** Ethicon, Engineering Fellow. (October 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Vincent Lucente:** Ethicon, Key Opinion Leader. (November 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Jorge Holste:** Ethicon, Principal Scientist. (December 2012. Attorney Roger Cameron: document review; deposition preparation; attended deposition; prepared summary of testimony.)
- **Susan Lin:** Ethicon, Manager, Regulatory Affairs. (March 2013. Attorney Roger Cameron: review, analyze key documents and database for deposition; attended deposition.)
- **Bryan Lisa:** Ethicon, Associate Director, Regulatory Affairs. (April 2013. Attorney Roger Cameron: review, analyze key documents and database for deposition; attended deposition.)
- **Jennifer Paine:** Ethicon, Worldwide Director of Regulatory Affairs. (June 2013. Partner Lee Balefsky, Attorney Roger Cameron: document review; deposition preparation; analyzed Arnaud document productions; Mr. Balefsky attended the deposition and examined the witness.)
- **Dan Burkley:** Ethicon, Principal Scientist. (May 2013. Attorney Roger Cameron: review, analyze key documents and database for deposition; attended deposition.)
- **Patricia Beach:** Ethicon, Clinical Project Manager. (May 2013. Attorney Roger Cameron: review, analyze key documents and database for deposition; attended deposition.)
- **Renee Selman:** Ethicon, Worldwide President, Women's Health and Urology.
- **Allison London Brown:** Ethicon, Worldwide Director of Marketing. (May 2012. Attorney Roger Cameron, document review; deposition preparation; Mr. Cameron attended deposition.)
- **Gregory Jones:** Ethicon, Product Development. (June 2013. Partner Lee Balefsky, Attorney Roger Cameron: review, analyze key documents and database for deposition; prepare deposition outline; Mr. Balefsky conducted the deposition.)
- **Scott Finley:** Ethicon, Divisional Sales Manager. (April 2013. Attorney Roger Cameron: review, analyze key documents and database for deposition; attended deposition.)

22. Many of these depositions were played at the various bellwether trials and form the basis of the design defect and failure to warn claims.

23. The deposition work performed by Kline & Specter attorneys was routinely recognized by members of the PSC as being crucial to case theory and development. Kline & Specter was continually recognized for its excellent work in this area. For example:

- a. On February 17, 2013, Thomas Cartmell asked PSC members to participate in MDL depositions. Lee Balefsky writes “Tom we will certainly participate. Bryan has already assigned us a deposition that Roger will cover.” Mr. Cartmell responds, “That is fine. We aren’t worried about you guys!” (*See* February 17, 2013 email, attached as Exhibit “5.”)
- b. On February 14, 2013, Bryan Aylstock asks Kline & Specter to cover the 30(B)(6) depositions on the Ex-US documents for Ethicon. Roger Cameron responds, “Our pleasure, Lee will be out of town that day so I will cover it.” (*See* February 14, 2013 email, attached as Exhibit “6.”)
- c. Attorneys from Kline & Specter provided key documents and analysis for the 2013 deposition of Catherine Beathe, Vice President of Ethicon, Worldwide Quality Assurance and Regulatory Affairs. Roger Cameron, “We’ve got great material, BSI Audit, CAPA, etc.” Kirk Goza, of Goza & Honnold responds, “Roger – Thanks for this summary. I have now freed up and will begin looking at docs you sent. I have seen many but not all of the Australian docs but many call you next week to go over. Thanks for all the hard work and will be in touch.” Mr. Goza further writes, “Roger hate to impose but quick question for you. On June 25 you sent me a nice summary of the Secur design validation disaster. Yale asked for studies to be done again which appears to have occurred. However, it also appears to have been after the 510(K) approval. Also, you raise a number of issues even with the second study. I wonder if we could talk about this for a few minutes before Yales depo next week. Also, any

additions you have for questions or to your summary would be very much appreciated. I think you have a better grasp of those studies than I do. I also should have you talk to Jerry in our office and we can work this up further if necessary. I know I should just get off my lazy tush and do it myself but I am always.” (See 2013 Catherine Beathe emails, attached as Exhibit “7.”)

- d. In August 2013, Lee Balefsky deposed Ethicon’s Gregory Jones, in charge of Product Development. Roger Cameron provided all firms with a substantive update of the deposition. “Great work gentlemen! Sounds like an interesting read!” Jeff Kuntz: “Awesome. Thanks guys. Will get Blume and Pence reports. Send any documents you came across or used that may be good.” Bryan Aylstock: “Great work. Definitely want to read. Can you get a cut done together with any key admissions for the expert?” (See August 21, 2013 email, attached to Exhibit “8.”)
- e. Regarding the deposition of Peter Cecchini, Ethicon Regulatory Affairs, Richard A. Frees of Freese & Goss writes, ““Thanks Roger. You did awesome. Getting the hernia 510 out was brilliant.” (See October 24, 2013 email, attached as Exhibit “9.”)

III. THE SECANT STORY

- 24. Secant Medical, Inc. (“Secant”) is a Pennsylvania corporation with its headquarters and manufacturing facilities located in Bucks County, Pennsylvania.
- 25. Ethicon had a long standing relationship with Secant regarding the design, manufacture, knitting and supply of the mesh used in its pelvic mesh devices.
- 26. In May 2013, Kline & Specter began filing cases involving transvaginal mesh devices in the Philadelphia Court of Common Pleas (“PCCP”). Named as defendants were both Ethicon and Secant.

27. Up until 2013, the vast majority pelvic mesh litigation against Ethicon was confined to the cases filed in the MDL and New Jersey. It was important for the common benefit to open a third venue of litigation.
28. The key to filing these cases in Philadelphia was Secant, a Pennsylvania company that played a vital role in the manufacture of Ethicon's pelvic mesh devices.
29. In July 2013, Secant filed Preliminary Objections, claiming that it was immune to liability in the litigation due to provisions of the Biomaterials Assurance Act ("BAAA"), 21 U.S. C. §1601. Secant claimed it was not a manufacturer of the mesh, only a biomaterials supplier.
30. Philadelphia Court of Common Pleas Judge Massiah-Jackson allowed Kline & Specter discovery regarding the Secant connection to this litigation. Secant produced tens of thousands of documents, which were accessible to all firms in this litigation, and Kline & Specter attorneys conducted the review of the Secant productions.
31. The treasure-trove of documents produced by Secant, the manufacture of the majority of the mesh used by Ethicon in the devices at issue in this litigation, proved vital in discovering the true pelvic mesh story.
32. The documents produced by Secant and the work performed by Kline & Specter established the company's connection with Ethicon and bolstered the arguments that the mesh was defective by providing information on, *inter alia*, the mesh knit, the porosity, and alternative mesh designs. (For example: *See* Secant's "Ultrapro Business Continuity" PowerPoint which provides an overview of manufacturing and validation activities at Secant for the Ultrapro Mesh, an alternative mesh design used by Ethicon, attached as Exhibit "10"; *see also* Secant's "Overview of Secant Medical" PowerPoint, used to show the mechanical aspects of the weaving, scouring, heatsetting, scouring, and other technical aspects of the mesh manufacturing, attached as Exhibit "11.")

33. Ethicon vigorously fought the propriety of over 100 lawsuits in Philadelphia County. Ethicon removed the cases to Federal Court claiming fraudulent joinder regarding the naming of Secant as a Defendant. Kline & Specter filed extensive briefing, defeating Ethicon's fraudulent joinder argument, and was able to effectively remand these cases back to the PCCP, thus concretely establishing the Pelvic Mesh Mass Tort program in Philadelphia.
34. The importance of the Ruling was not lost on Ethicon, who asked Judge Goodwin to certify an Interlocutory Appeal (which was denied).
35. Lee Balefsky emailed members of the PSC: "Huge win! Goodwin remanded Secant cases back to Philly!" This work by Kline & Specter and the importance of the establishment of the PCCP pelvic mesh mass tort program was recognized by key members of the PSC as a "game changer!!!" (Bryan Aylstock) and "Fantastic!!" (Justin Witkin) and "Wow! Great!" (Fidelma Fitzpatrick) Other members replied "Boom!!" (Doug Kreis). And Thomas Cartmell wrote, "Ha. Love it! Best news I've had in a long time. .. wow this is crazy good!" (*See* December 19, 2013 email from Lee Balefsky to PSC members, attached as Exhibit "12.")
36. However, Ethicon was not done its fight, and, in September of 2014, Ethicon filed a Motion to Dismiss 118 single-plaintiff cases in the mass tort proceedings in the PCCP asserting lack of personal jurisdiction.
37. After months of substantial legal work, including oral argument by Kline & Specter attorney Charles Becker, Judge Arnold New denied Ethicon's Motion to Dismiss and overruled Preliminary Objections (also asserting lack of jurisdiction) by Orders on March 30, 2015. It is clear that Secant's manufacture of the mesh in Pennsylvania established a significant contact with Johnson & Johnson, Ethicon, and the Commonwealth of Pennsylvania. Kline & Specter successfully managed to keep the 118 cases in the PCCP – maintaining another avenue for

litigating these cases against Ethicon and establishing further pressure on this defendant to the benefit of all pelvic mesh litigants.

38. Once again, PSC members were enthusiastic with the result, praising Kline & Specter for its hard fought win after being informed, “We just received a great ruling from J. New in the Philly mass tort program denying Ethicon/J&J motions to dismiss for lack of jurisdiction. That means eight (8) trials, scheduled to begin in Nov, will move forward. . . “ From Bryan Aylstock, “That’s great news!!”. From Richard Freese, “That’s great Lee. I’m available for a conf. call to discuss.” From Adam Slater, “Wow. Sounds solid.” (See March 31, 2015 emails, attached as Exhibit “13.”)
39. In 2017, the Supreme Court of the United States ruled in favor of defendants on two cases regarding personal jurisdiction: *Bristol-Myers Squibb Co. v. Superior Court of California* and *BNSF Railway Co. v. Tyrrell*. Following these rulings, Ethicon filed a Motion for Reconsideration regarding Judge New’s 2015 Order allowing the cases to proceed in Philadelphia.
40. After significant motion practice, on September 15, 2017, Judge New directed briefing and asked both Kline & Specter and Ethicon whether Secant is the exclusive provider of mesh used in Defendants’ pelvic mesh medical devices in order to determine the mesh supply chain for Ethicon as relates to the Plaintiffs whose pelvic-mesh claims were pending before the Court.
41. Over Ethicon’s objections, Lee B. Balefsky of Kline & Specter took the deposition of James O. Williams, Ethicon’s former Strategic Sourcing Manager. Mr. Balefsky was able to successfully obtain the key testimony from Mr. Williams that indeed, all the mesh used by Ethicon in its pelvic mesh products (with the exception of Prolift + M) was manufactured by

Secant, in the Commonwealth of Pennsylvania. This testimony would prove essential in defeating Ethicon's motion to remove the pelvic mesh cases from Philadelphia.

42. After this exhaustive and extensive motion practice and oral argument by Kline & Specter attorney, Charles Becker, it was determined that with the exception of the few cases involving the Prolift + M, all mesh products involved in the (now) 106 Ethicon cases pending before the PCCP were manufactured by Secant, in Pennsylvania, thus establishing jurisdiction of the Pennsylvania courts.

43. The "Secant Story" and resulting litigation against Ethicon in Philadelphia were critical to the Common Benefit of all plaintiffs. More cases have been tried against Ethicon in the PCCP than both the MDL and NJ combined. These cases have been hugely successful. This stalwart effort by Kline & Specter forced Ethicon to divert resources from litigations in other venues and ultimately has likely been critical in the settlements of thousands of cases.

IV. DEVELOPMENT OF EXPERTS

44. Utilizing their medical, scientific and bioethics training, our attorneys, including our physician-attorneys, committed extensive time to this litigation working with experts to develop expert reports, prepare for depositions and trial testimony, and hone and improve their impact upon this litigation.

45. Kline & Specter attorneys helped develop the experts who proved valuable throughout the pelvic mesh litigation and were utilized by other attorneys and firms involved in this litigation.

46. Specifically, the experts developed by Kline & Specter attorneys in whole or in part are as follows:

- a. Ralph Zipper, M.D., FACOG, FPMRS – Urogynecology. (Testified in *Hammons v. Ethicon*.)

- b. Bruce Rosenzweig, M.D. - Urogynecology. (Testified in numerous bellweather and state court trials, including in the MDL and the Philadelphia Court of Common Pleas.)
 - c. Michael Thomas Margolis, M.D. – Urogynecology. (Testified in numerous bellweather and state court trials, including in the MDL and the Philadelphia Court of Common Pleas.)
 - d. Peggy Jo Clark Pence, Ph.D – FDA/Regulatory. (Testified in: numerous bellweather and state court trials, including in the MDL.)
 - e. Richard S. Bercik, M.D. – Urogynecology. (Testified in Delaware state court.)
47. This work, as discussed in Section V below, by Kline & Specter attorneys included preparing experts for depositions, refining testimony, preparing deposition cuts for use in trials, and assisting with the draft of reports. Kline & Specter’s involvement in the development of experts was routinely recognized by members of the PSC. (See October 13, 2013 email from Jeffrey Kuntz of Wagstaff & Cartmell: “Thanks a ton! I think it is taking shape. You guys will love all the final reports! I really appreciate the help.”, attached here as Exhibit “14.”)

V. TRIALS IN THE PELVIC MESH LITIGATION

Gross v. Ethicon

48. In February 2013, Attorneys at Kline & Specter provided assistance to Adam Slater of Mazie Slater and his team during *Gross v. Ethicon* No. ATL-L-6966-10, N.J. Super., Atlantic Co. Kline & Specter attorneys provided assistance in all aspects of litigation support and attorney Roger Cameron traveled to New Jersey to assist in person. (See January 20, 2013 email from Adam Slater, “Roger can you please help? Need a list of materials review and page count for Klinge.”, attached as Exhibit “15.”)

49. As the only firm to “step up”, Kline & Specter attorneys were recognized for their significant work in the *Gross* trial. (See January 25, 2013, email exchange between Adam Slater, Esquire and Lee Balefsky regarding Kline & Specter’s assistance in the *Gross v. Ethicon* trial, attached as Exhibit “16.” Lee Balefsky: “Adam, wanted to let you know that you guys are doing a great job. We are happy to be part of the ‘team.’ Let us know what, if anything, you need done.” Adam Slater: “Thanks a lot Lee. I’m sure we will need more help. Great team effort.”)

Lewis v. Ethicon

50. In February 2014, attorneys from Kline & Specter also assisted Thomas Cartmell of Wagstaff & Cartmell and the trial team in *Lewis v. Ethicon* 2:12-cv-04301 (S.D.W. Va. 2014) Despite the defense verdict, work from this trial paved the way for trying cases involving Ethicon’s TVT devices. (See February 20, 2014 emails from Thomas Cartmell and Adam Faes, attached as Exhibit “17.” “Roger, I just wanted to take a few minutes and thank you for all your hard work and assistance. Despite the result in the Lewis case, your hard work will not go to waste.” “Thanks for all your help Roger – really appreciate it.”)

Hammons v. Ethicon

51. In December 2015, Kline & Specter founding partner, Shanin Specter and partner Kila Baldwin, and Mazie Slater attorney Adam Slater, tried the first case against Ethicon in the PCCP - *Hammons v. Ethicon Inc.*, No. 130503913. The *Hammons* case was the second Prolift trial in the country, and the Kline & Specter attorneys who worked on this case were responsible for developing a trial package for the Prolift that covered the essential parts of the liability theories, including design defect, failure to warn, alternative design, and foreseeable misuse.

52. The *Hammons* trial team successfully defeated several important motions by Ethicon in the pre-trial phase, setting precedent for the admissibility of expert testimony and evidence in future Ethicon cases:

- a. Ethicon's Motion to Exclude the Testimony of Peggy Pence, Ph.D., was denied;
- b. Ethicon's Motion to Exclude the Testimony of Anne Weber, M.D., was denied;
- c. Ethicon's Motion to Exclude the Testimony of Prof. Dr. Uwe Klinge, was denied;
- d. Ethicon's Motion to Exclude the Testimony of Daniel S. Elliott, M.D., was denied;
- e. Ethicon's Motion to Exclude the Testimony of Ralph Zipper, M.D., was denied; and
- f. Ethicon's Motion for Partial Summary Judgment on Punitive Damages was denied.

53. During the *Hammons* trial, Shanin Specter was able to effectively establish the following key points for the jury:

- a. The Prolift device was defectively designed due to its use of a small pore, heavy weight polypropylene mesh, its overall amount of mesh material, and the inability of the device to incorporate safely into the female pelvis;
- b. Ethicon knew of the risk of the permanent and severe risks of the Prolift, including the risk of lifelong dyspareunia, prior to the Prolift launch in 2005 and failed to warn doctors and patients of these risks;
- c. Ethicon placed the product on the market before it fully understood how it would work and then delayed its withdrawal even as evidence mounted that it was severely injuring women; and

- d. Ethicon destroyed thousands of pages of documents that were on a litigation hold— a fact that had not been presented in any other Prolift trial before and that had obvious value for punitive damages awards.

- 54. After a two and a half week trial, the jury in *Hammons* found that the Prolift was defectively designed, that Ethicon failed to properly warn of the risks of the device, and that Ethicon was liable for punitive damages. The *Hammons* case was the first time that a jury ever found for the plaintiff on a defective design claim in a Prolift trial – a monumental achievement which established the viability of design defect claims in all Prolift cases going forward.
- 55. The jury awarded Mrs. Hammons \$5.5 million in compensatory damages and \$7 million in punitive damages, which was the largest Ethicon jury verdict to date and the third largest plaintiff verdict in the entire pelvic mesh litigation.
- 56. The deposition “cuts” from the *de bene esse* depositions of expert witnesses such as Dr. Daniel Elliot and Prof. Uwe Klinge, which were created by the *Hammons* trial team and played during the *Hammons* trial, were deemed admissible to be used in Prolift Wave cases by Magistrate Judge Cheryl A. Eifert of the United States District Court for the Southern District of West Virginia.
- 57. Subsequently, attorneys around the country requested and used portions of the *Hammons* trial package, including deposition outlines prepared by Kline & Specter partner, Kila Baldwin, Esq., for their Ethicon MDL Wave cases.
- 58. The *Hammons* trial and its groundbreaking verdict against Ethicon established the Philadelphia litigation as a serious threat to Ethicon, requiring Ethicon to expend significant resources in the defense of these cases before Philadelphia juries.

Carlino v. Ethicon

59. In January 2016, Kline & Specter founding partner, Shanin Specter, and partners Kila Baldwin and Michael Trunk, and Freese & Goss attorney Richard Freese, tried the first TVT retropubic sling case in the PCCP - *Carlino v. Ethicon Inc.*, No. 130603470.
60. *Carlino* was the first TVT case to go to a jury and resulted in what was the largest verdict for an Ethicon stress urinary incontinence product to date. The jury awarded Mrs. Carlino \$3.25 million in compensatory damages, \$250,000 to Mr. Carlino for loss of consortium, and \$10 million in punitive damages.
61. As a result of extensive pre-trial briefing and oral argument, the *Carlino* trial team was able to achieve favorable rulings from the trial court on dispositive motions and motions *in limine* which would prove to benefit pelvic mesh litigants in other mesh cases throughout the various jurisdictions.
62. For example, Ethicon's Motion for Partial Summary Judgment on Plaintiffs' failure to warn claim was denied, allowing, for the first time, a jury to consider the adequacy of the warnings that accompanied the TVT device.
63. Over the course of the twelve day trial, Plaintiffs successfully defeated Ethicon's claim that the TVT device, a product on the market since 1998, was the "gold standard" for treatment of stress urinary incontinence. The jury ultimately concluded that the TVT was defectively designed and that Ethicon had failed to warn physicians of the TVT's medical risks.
64. Again, the trial package prepared by Kline & Specter attorneys for *Carlino* was highly sought after for other TVT cases across the country. The deposition designations created by the Kline & Specter attorneys for *Carlino* were utilized by other attorneys in preparing for New Jersey and MDL trials, and the rulings Kline & Specter attorneys

were able to obtain on Ethicon's pre-trial motions, including motions *in limine*, were relied upon for cases in the MDL and other district courts.

Engleman v. Ethicon

65. In April 2017, *Engleman v. Ethicon, Inc.*, No. 140305384, was the first TVT-Secur PCCP trial with Aylstock, Witkin, Kreis, & Overholtz, Anderson Law Offices, and Kline & Specter serving as Plaintiffs' counsel.

66. Kline & Specter partner, Christopher Gomez, served as trial counsel along with Ben Anderson of Anderson Law Offices and Daniel Thornburgh of Aylstock, Witkin, Kreis & Overholtz and assisted in all aspects of trial preparation, including development of the legal strategy and pre-trial briefing. At trial, Gomez cross-examined defense expert, Brian J. Flynn, M.D., an urologist who testified that the TVT and TVT-Secur slings were not the cause of Mrs. Engleman's pelvic complaints.

67. *Engleman* was also the first TVT-Secur case to be tried to a jury verdict and resulted in a \$20 million verdict (\$2.5 million in compensatory damages and \$17.5 million in punitive damages).

68. As the third straight loss for Ethicon in the Philadelphia litigation, with each case resulting in a larger verdict than the last, *Engleman* served as an important reminder to Ethicon that the PCCP cases would continue to be a major threat to the defendant in the pelvic mesh litigation.

Beltz v. Ethicon

69. In May 2017, Kline & Specter founding partner, Thomas R. Kline and partner Kila Baldwin tried the second Prolift trial in the PCCP, *Beltz v. Ethicon, Inc.*, No. 130603835. The jury awarded Mrs. Beltz \$2.16 million in compensatory damages.

Ebaugh v. Ethicon

70. Most recently, in September 2017, Kline & Specter partner, Kila Baldwin along with associates, Tracie Palmer and Elia Robertson represented the plaintiff, Ella Ebaugh, through a five-week long trial in *Ebaugh v. Ethicon, Inc.* No. 130700866, a case involving both the TVT and TVT-Secur devices.

71. An essential part of preparing the Ebaugh case for trial was refining the de bene esse deposition testimony of Dr. Bruce Rosenzweig, Plaintiff's expert urogynecologist who testified on the defective design of the TVT and TVT-Secur devices. Baldwin, Palmer, and Robertson spent significant time revising the deposition "cuts" of Dr. Rosenzweig's testimony in order to present the most compelling expert testimony regarding the TVT-Secur that could be used in all TVT-Secur cases going forward.

72. Through the *Ebaugh* trial, Kline & Specter attorneys obtained the largest verdict against Ethicon to date - \$57.1 million (\$7.1 million in compensatory damages and \$50 million in punitive damages).

VI. ADDITIONAL COMMON BENEFIT WORK

In re: Boston Scientific Corporation

73. Kline & Specter was and continues to be actively involved in the litigation against Boston Scientific Corporation ("BSC") including the work-up of the MDL wave cases.

74. Kline & Specter was and continues to be actively involved in the Massachusetts and Delaware litigation against BSC.

75. Beginning in 2012, attorneys at Kline & Specter devoted extensive hours to the review of documents produced by BSC and providing subjective coding of those documents.

In re: C.R. Bard

76. Kline & Specter attorneys were also involved in the work-up of MDL Wave cases against Bard for bellwether trials, including the following:

- a. Performing document review and analysis and assisting in key depositions including the following C.R. Bard corporate witnesses:

- Gary Teague, C.R. Bard, Marketing Director.
- Mary Mayo, C.R. Bard, Vice President of Quality Assurance.
- Dough Evans, C.R. Bard, Research & Development.
- John Knorpp, C.R. Bard, Director of Regulatory Affairs.
- Scott Britton, C.R. Bard, Vice President Research and Development, Urological Division.
- Brian Berry, C.R. Bard, Vice President Regulatory and Clinical Affairs.
- Dr. Ciavarella, C.R. Bard, Vice President Corp. Clinical Affairs.
- Roger Darios C.R. Bard, Engineering.

- b. Helped draft discovery motions and responses.

In re: Coloplast

77. While lead Coloplast MDL attorneys did virtually no discovery against Coloplast, choosing instead to participate in their settlement program, Kline & Specter pursued vigorous discovery against Coloplast to the benefit of all remaining Coloplast litigants.

78. Kline & Specter was the only firm in this litigation who did any discovery against Coloplast.

79. Kline & Specter attorneys reviewed millions of pages of documents and deposed the following corporate witnesses:

- a. Julie Kerkvliet: Coloplast, Senior Global Group Marketing Manager
- b. Ash Keswani: Coloplast, Director of Global Marketing
- c. Stephan Hovard: Coloplast, Senior Vice President, Urology Care

VII. OBSERVATIONS REGARDING OVERALL COMMON BENEFIT WORK AND 5% FEE

80. The overall work of the attorneys involved in the pelvic mesh mass tort litigation did not result in a Global Settlement. Instead, individual firms negotiated piecemeal settlements.

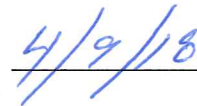
81. While Kline & Specter has requested the total amount of all settlements, this information has not been provided by the FCC.
82. Kline & Specter has reason to believe that the per case settlement average is approximately \$40,000.
83. Many of the settlements were wholly inadequate for a substantial number of plaintiffs, considering the seriousness and permanence of their injuries and the courtroom track record of verdicts for these cases.
84. American Medical Systems (“AMS”) cases were settled at an early stage because of the perceived financial condition of the company.
85. Coloplast entered into an early settlement program whereby no discovery was ever conducted in the MDL.
86. Kline & Specter’s per case settlement average is approximately \$75,000, almost double the overall average. If we removed Kline & Specter’s involvement in the AMS settlement, our per case average would be \$120,000.
87. Kline & Specter and its clients have contributed over \$5,000,000 to the Common Benefit Fund as a result of its settlements.
88. Kline & Specter’s five (5) verdicts totaled \$110,000,000, increasing Kline & Specter’s per case average to \$155,000 including the AMS settlement. Without including the AMS settlement, Kline & Specter’s per case average rises to \$315,000.
89. Kline & Specter, their clients, and other firms who did critically important work and achieved superior results have been vastly overcharged at the 5% rate.
90. Kline & Specter believes that the Common Benefit Fee percentage should be reduced and the money returned to the clients and law firms.

91. The above discussion is another reason why it is critical for all firms involved in this litigation to be permitted to have information to allow for a fair and transparent process including:

- a) Production of each fee and expense request of each firm;
- b) The FCC's response to each request;
- c) Disclosure of the amount of money received pursuant to the 5% assessments along with per firm itemizations of these payments;
- d) All documents and emails relating to any fee sharing agreements between or amount the members of the FCC;
- e) All communications among FCC members and all document relating to FCC consideration of the fee and expense reports; and
- f) All communications between the FCC and fee requesting firms.



Lee B. Balefsky



Date

Kline & Specter, P.C.

Sworn and subscribed before me

this ^{9th} day of April 2018.

